Section I 510(k) Summary of Safety and Effectiveness K042522

Applicant:

Draeger Air Shields Infant Care Inc.
330 Jacksonville Road
Hatboro, Pa. 19040
Registration No: 2510954

JUL 6 - 2005

Contact Person:

Thomas McIntosh
Ph 215-682-8634
Fax 215-682-8689

Device trade/proprietary name:

Minolta Draeger Air Shields JM 103

Device common / usual/ classification name:

Jaundice Meter

Classification:

Clinical Chemistry Test Systems
21 CFR 862.113
Bilirubin in the Neonatal Test System, MQM, Class I

Performance Standards:

None applicable

Predicate Device:

K021622 JM 103 Jaundice Meter

Device Description

The JM-103 Jaundice Meter is designed to provide a transcutaneous measurement of bilirubin displayed in Mg/dl or μmol/L. This measurement is intended as a screening tool to determine when a serum bilirubin measurement should be taken, or, sequential bilirubin measurements over time to provide indication of change. This device is not intended for determinations of whether treatment is indicated. The determination of treatment must be based on a serum bilirubin measurement.

Description of Modifications:

No modification to hardware, software, or procedures for use were implemented for this submission on the JM 103 Device previously cleared by the FDA as a medical device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

JUL 6 - 2005

Mr. Thomas McIntosh
Regulatory Affairs
Draeger Air Shields Infant Care, Inc.
330 Jacksonville Road
Hatboro, PA 19040

Re: k042522
Trade/Device Name: JM 103 Jaundice Meter
Regulation Number: 21 CFR § 862.1113
Regulation Name: Bilirubin (total and unbound) in the neonate test system
Regulatory Class: I
Product Code: MQM
Dated: March 24, 2005
Received: April 11, 2005

Dear Mr. McIntosh:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820).

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific information about the application of labeling requirements to your device, or questions on the promotion and advertising of your device, please contact the Office of In Vitro Diagnostic Device Evaluation and Safety at (240) 276-0484. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Carol C. Benson

Carol C. Benson, M.A.
Acting Director
Division of Chemistry and Toxicology
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K042522

Device Name: JM 103 Jaundice Meter

A.1 Indication for Use Statement

The Jaundice Meter (JM-103) is a non-invasive transcutaneous bilirubinometer. It measures yellowness of subcutaneous tissue in newborn infants. The unit provides a visual digital measurement that has been shown to correlate with serum bilirubin in newborn infants.

The device is intended for use in hospitals, clinics or doctor's offices under a physicians supervision / direction to assist clinicians in monitoring of newborn infants. The device is not intended as a standalone for diagnosis of hyperbilirubinemia. It is to be used in conjunction with other clinical signs and laboratory measurements.

Newborn infants whose JM-103 Jaundice Meter test results are indicative of hyperbilirubinemia should be evaluated by their physician(s) for appropriate patient management. Specific neonatal patient Bilirubin levels should be confirmed by other methods, such as serum bilirubin, prior to treatment determinations.

The JM 103 is a prescription Medical Device
The JM 103 is not intended for home use.
The JM 103 may only be used at the sternum measurement site for Physician's office applications.

Prescription Use ✓ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Division Sign-Off

Office of In Vitro Diagnostic Device Evaluation and Safety

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